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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/667,936 | 09/22/2003 | John Moberg | 1001.1715101 | 1606 |
| 28075 7590 08/31/2010 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | | |
| EXAMINER | | | | |
| LALLI, MELISSA LYNN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3728 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 08/31/2010 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/667,936

Applicant(s)

MOBERG, JOHN

Examiner

MELISSA L. LALLI

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-10, 13, 19-21 and 26-29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 26 and 27 is/are allowed.
6) ☒ Claim(s) 1-4, 7-10, 13, 19-21, 28 and 29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Drafts/Person's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. This is in response to applicant's amendment wherein claims 1, 10, and 27 have been amended and claim 11 has been canceled. Therefore, claims 1-4, 7-10, 13, 19-21, and 26-29 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2010 has been entered.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "interference fit structure" including "a first portion having an outer diameter" and "a second portion having an outer diameter different from the outer diameter of the first portion" wherein "at least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring" as stated in claim 1 must be shown or the feature(s) canceled from the claim(s). Also, the "interference fit structure" including "a first portion" and "a second portion" wherein "at

least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring" and the "interference fit structure" being "helically disposed about the hub assembly" within a "helical channel" as stated in claims 28 and 29 must be shown or the feature(s) canceled from the claim(s). Additionally, the "interference fit structure" including "a first portion" and "a second portion" wherein "at least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring" and the "interference fit structure" being "an elongated elastomeric sleeve having an outer circumference that varies along a length of the elongated elastomeric sleeve" as stated in claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the "interference fit structure" including "a first portion having an outer diameter" and "a second portion having an outer diameter different from the outer diameter of the first portion" wherein "at least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring" as stated in claim 1 is not supported in the specification. Also, the "interference fit structure" including "a first portion" and "a second portion" wherein "at least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring" and the "interference fit structure" being "helically disposed about the hub assembly" within a "helical channel" as stated in claims 28 and 29 is not supported in the specification. Additionally, the "interference fit structure" including "a first portion" and "a second portion" wherein "at least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring" and the "interference fit structure" being "an elongated elastomeric sleeve having an outer circumference that varies along a length of the elongated elastomeric sleeve" as stated in claim 13 is not supported the specification. In each instance above,

applicant appears to be combining various embodiments of the invention which are not supported in the original disclosure.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4, 7-10, 13, 28, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, the limitation "the interference fit structure" including "a first portion having an outer diameter" and "a second portion having an outer diameter different from the outer diameter of the first portion" wherein "at least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring" is considered new matter because there is no support for the different embodiments disclosed in figs. 6e, 6f, or 6i each combined with figs. 7-7b. There is support for such language as separate embodiments; however, applicant has created a new matter situation by combining said separate embodiments to form an additional alternate embodiment of an interference fit member having first and second portions of different outer diameter wherein at least one of the first and

second portions is a non-continuous ring having a gap. Applicant is required to clarify and amend the claims as necessary.

Claim 13, the limitation "the interference fit structure is an elongated elastomeric sleeve having an outer circumference that varies along a length of the elongated elastomeric sleeve" is considered new matter with respect to the IFM being a "non-continuous ring having a gap" as stated in claim 1 because there is no support for the combination of the different embodiments disclosed in fig. 6i and figs. 7-7b of the specification. There is support for such language as separate embodiments; however, applicant has created a new matter situation by combining said separate embodiments to form an additional alternate embodiment of an interference fit member which is an elongated elastomeric sleeve as well as a non-continuous ring having a gap. Applicant is required to clarify and amend the claims as necessary.

Claims 28 and 29, the limitations "the interference fit structure is helically disposed about the hub assembly" and "the interference fit structure is disposed in a helical channel" are considered new matter with respect to the IFM being a "non-continuous ring having a gap" as stated in claim 1 because there is no support for the combination of the different embodiments disclosed in fig. 6j and figs. 7-7b of the specification. There is support for such language as separate embodiments; however, applicant has created a new matter situation by combining said separate embodiments to form an additional alternate embodiment of a helically disposed interference fit member which is also a non-continuous ring having a gap. Applicant is required to clarify and amend the claims as necessary.

8. Claims 1-4, 7-10, 13, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations "the interference fit structure" including "a first portion having an outer diameter" and "a second portion having an outer diameter different from the outer diameter of the first portion" wherein "at least one of the first and second portions comprises a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring". It is unclear what structure is encompassed by first and second portions of the IFM having different outer diameters with respect to at least one of the first and second portions being a "non-continuous ring having a gap". There is no support for the combination of the two alternate embodiments in the original specification.

Regarding claim 10, the limitation "the interference fit structure includes a bead adhered to the first portion" is indefinite and misleading. Is the "bead" equivalent to either of the "first portion" or "second portion" elements of claim 1? Or is the "bead" a separate element additional to the first and second portions? From fig. 6d which appears to show the "bead adhered to the first material", there only appears to be one portion which does not have varying diameters. Is applicant mixing the different configurations shown through figs. 6a-6j? If so, there must be sufficient support in the specification to combine the varying configurations of the interference fit structure. Furthermore, it is unclear as to what is being claimed. For examination purposes, it will be assumed that one of the first or second portions is a bead adhered to the first

material of the hub assembly; however, applicant is required to clarify and amend the claim as necessary.

Claim 13 recites the limitation the "interference fit structure is an elongated elastomeric sleeve having an outer circumference that varies along a length of the elongated elastomeric sleeve " on lines 2-3. It is unclear what structure is encompassed by "elongated elastomeric sleeve" as stated in line 2 with respect to the interference fit member also being a "non-continuous ring having a gap" as stated in claim 1. There is no support for the combination of the two alternate embodiments in the original specification.

Claims 28 and 29 recite the limitations the "the interference fit structure is helically disposed about the hub assembly" and "the interference fit structure is disposed in a helical channel". It is unclear what structure is encompassed by "helically disposed" and "disposed in a helical channel" as stated respectively in line 2 of each claim with respect to the interference fit member also being a "non-continuous ring having a gap" as stated in claim 1. There is no support for the combination of the two alternate embodiments in the original specification.

Claim Rejections - 35 USC § 103

9. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,214,220 to McGlinch et al. (McGlinch) in view of US 5,217,114 to Gadberry et al. (Gadberry) and US 4,130,304 to Hebard.

Regarding claim 19, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface,

the elongate medical device comprising: an elongate shaft (22) having a proximal portion and a distal portion; a hub assembly (30) connected to the proximal portion of the elongate shaft such that the elongate shaft extends distally from the hub assembly, the hub assembly including a portion manufactured from a first material (col. 3, lines 13-18); and a circumferential IFM (40) configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the hub assembly including a circumferential channel and the IFM being disposed in the circumferential channel; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with a circumferential IFM (65) disposed in a circumferential channel (64). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the circumferential channel (64) and IFM (65) arrangement of Gadberry for the IFM (40) on the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to maintain the seal when the elongate medical device is enclosed within the tubular member as taught by Gadberry.

Additionally, neither McGlinch nor Gadberry discloses the circumferential interference fit member including a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring; however, Hebard discloses an interference fit member (54) including a non-continuous ring (see split at 112) used as a frictional coupling mechanism for tubing. It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted a non-continuous

ring for the IFM of McGlinch and Gadberry in order to facilitate application of the IFM to the hub of the elongate medical device of McGlinch and Gadberry as taught by Hebard (col. 4, lines 12-13). The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It is unclear whether Hebard discloses a gap between a first portion of the ring and a second portion of the ring; however, it is inherent/obvious that a gap would be created between first and second end portions of the ring dependent on the diameter of the ring and the diameter of the structure to which it is applied. Additionally, it is inherent/obvious that the gap allows the first portion of the ring to be deflected toward the second portion of the ring when the circumferential IFM is disposed in the lumen of the tubular member since the IFM is formed of a deformable material (Gadberry; figs. 3 and 6, the IFM is readily deformable compared to the tubular member).

Regarding 20 and 21, McGlinch discloses the hub assembly (30) comprising a manifold (32) with a distal portion including the first material where the IFM is disposed about the distal portion of the manifold. A strain relief member (34) is integrally formed with the manifold (col. 3, lines 9-13).

10. Claims 1-4, 7-10, and 13 (as best understood) are rejected under 35 U.S.C. 103(a) as being unpatentable over McGlinch in view of Gadberry, US 3,307,552 to Strawn, and Hebard.

Regarding claim 1, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface,

the elongate medical device comprising: an elongate shaft (22) having a proximal end and a distal end, the elongate shaft extending from a proximal portion of the elongated medical device to a distal portion of the elongated medical device; a hub assembly (30) including a proximal end and a distal end, the proximal end of the elongate shaft connected to the hub assembly such that the elongate shaft extends distally from the distal end of the hub assembly, the hub assembly including at least a portion manufactured from a first material (col. 3, lines 13-18); and an interference fit structure (40) disposed about at least a part of a portion of the hub assembly including the first material, and configured to contact and form an interference fit with an inner surface of a tubular member when the elongate shaft and the interference fit structure are disposed therein (fig. 1).

McGlinch discloses the interference fit structure (40) including a ring portion (42) and end portions (44) which have different outer diameters. It appears that the ring and end portions would allow tubular members of different diameters to connect to the hub assembly (col. 4, lines 4-18); however, if this is not apparent, Strawn discloses an elongated medical device (fig. 1) comprising a hub assembly (fig. 6) with an interference fit structure (38) including a first portion (fig. 6, first ring 38 starting from left) having an outer diameter and a second portion (fig. 6, second ring 38 starting from left) having an outer diameter different from the outer diameter of the first portion, the first portion of the interference fit structure configured to contact and form an interference fit with an inner surface of a generally tubular member (fig. 1, 12 for example) having a first inner diameter when the interference fit structure is disposed therein, and the second portion

of the interference fit structure configured to contact and form an interference fit with an inner surface of a generally tubular member having a second inner diameter different from the first inner diameter when the interference fit structure is disposed therein (col. 3, lines 3-12). It would have been obvious to one having ordinary skill in the art at the time of the invention to have formed the interference fit structure of McGlinch to have first and second portions having different diameters or multiple ring portions with varying outer diameters in order to accommodate tubular members having various diameters and hence, reducing manufacturing expenses by forming one device as taught by Strawn (col. 1, lines 38-46) instead of forming the device in a variety of sizes to engage with a specific, respective tubular member of corresponding size.

Additionally, it is unclear if the interference fit structure of McGlinch and Strawn includes a second material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an interference fit structure (65) formed on a hub assembly (61) and including a second, deformable material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have formed the first and second portions or multiple rings of the interference fit structure of McGlinch and Strawn of the second, deformable material as taught by Gadberry in order to create a stronger frictional seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36). Furthermore, it has been held that forming in one piece an article which has formerly been formed in two

pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Furthermore, McGlinch, Strawn, and Gadberry do not appear to disclose the circumferential interference fit member including a non-continuous ring having a gap between a first portion of the ring and a second portion of the ring; however, Hebard discloses an interference fit member (54) including a non-continuous ring (see split at 112) used as a frictional coupling mechanism for tubing. It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted a non-continuous ring for each of the first and second portions of the IFM of McGlinch, Strawn, and Gadberry in order to facilitate application of each of the first and second portions of the IFM to the hub of the elongate medical device of McGlinch, Strawn, and Gadberry as taught by Hebard (col. 4, lines 12-13). The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It is unclear whether Hebard discloses a gap between a first portion of the ring and a second portion of the ring; however, it is inherent/obvious that a gap would be created between first and second end portions of the ring dependent on the diameter of the ring and the diameter of the structure to which it is applied. Additionally, it is inherent/obvious that the gap allows the first portion of the ring to be deflected toward the second portion of the ring when the circumferential IFM is disposed in the lumen of the tubular member since the IFM is formed of a deformable material (Gadberry; figs. 3 and 6, the IFM is readily deformable compared to the tubular member).

Regarding claim 2, McGlinch discloses the hub assembly (30) having a distal portion including a segment with a generally circular cross section including a first material (fig. 1). Gadberry discloses the interference fit structure (65) being disposed about a channel (64) extending around a segment of the hub assembly (61) including a first material, wherein at least a portion of the interference fit structure is disposed in the channel. It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the channel (64) of Gadberry on the circular segment of the distal portion of the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal when the elongate medical device is enclosed as taught by Gadberry.

Regarding claims 3 and 4, McGlinch discloses the hub assembly (30) comprising a manifold (32) with a distal portion including the first material where the interference fit structure is disposed about the distal portion of the manifold. A strain relief member (34) is integrally formed with the manifold (col. 3, lines 9-13).

Regarding claims 7-10, Gadberry discloses the second material being more compressible than and readily deformable compared to the first material (figs. 3 and 6). Either of the first or second portions of the IFM is considered a bead adhered to the first material of the hub assembly.

Regarding claim 13, McGlinch appears to disclose the interference fit structure (40) being an elongated sleeve (42-44) having an outer circumference that varies along a length of the elongated sleeve. Strawn also discloses an elongated interference fit

member (fig. 4, 30) having an outer circumference that varies along its length.

Subsequent the modification in view Gadberry, the elongated interference fit structure may be formed as an elastomeric sleeve as per the second, deformable material of Gadberry. Additionally, a change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-4, 7-10, 13, and 19-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,214,220 in view of Gadberry and Hebard. Although the conflicting claims are not identical, they are not patentably distinct from each other because the incorporation of Gadberry and Hebard renders the claims obvious as substantially the same subject matter is recited. More specifically, it would have been obvious to one having ordinary skill in the art at the time of the invention to have formed the interference fit structure of McGlinch of the second, deformable material as taught by Gadberry in order to create a stronger frictional seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36). Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the circumferential channel (64) and interference fit member (65) arrangement of Gadberry for the IFM (40) on the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to maintain the seal when the elongate medical device is enclosed within the tubular member as taught by Gadberry.

Furthermore, substituting a non-continuous ring (54) having a gap (112) for the IFM of McGlinch and Gadberry would have obvious in order to facilitate application of the IFM to a structure as taught by Hebard (col. 4, lines 12-13).

Allowable Subject Matter

13. Claims 26 and 27 are allowed.

Response to Arguments

14. Applicant's arguments filed July 9, 2010 have been fully considered but they are not persuasive.

With respect to applicant's challenge of the examiner's use of Official Notice in the prior office action, Hebard has been provided to demonstrate that it is old and conventional to use split/gapped o-rings as a frictional coupling/connection mechanism for tubing structures in the art in order to facilitate application of the o-ring to a structure as is discussed in detail in the rejections above. It is further noted that Mertens et al. is cited as extrinsic evidence to demonstrate the use of such split/gapped o-rings (80 & 82; col. 7, line 54 - col. 8 - line 13) in the art of forming seals in medical devices.

With respect to applicant's arguments that the double patenting rejection of claims 1-4, 7-10, 13, and 19-21 is improper, the examiner respectfully disagrees. The specified double patenting rejection has been maintained as split/gapped o-rings are considered old and conventional in the art in view of Hebard.

15. Applicant's arguments filed July 9, 2010 with respect to the double patenting rejection of claims 26-29 have been fully considered and are persuasive. The double patenting rejection of claims 26-29 has been withdrawn.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA L. LALLI whose telephone number is (571)270-5056. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLL
8/28/10

/JILA M MOHANDESI/
Primary Examiner, Art Unit 3728